



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0159; FRL-9953-21]

Iron Oxide Yellow; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of iron oxide yellow (CAS Reg. No. 20344-49-4) when used as an inert ingredient (colorant) in pesticide formulations intended for varroa mite control around bee hives at a maximum concentration not to exceed 0.15% by weight in the pesticide formulation. Technology Sciences Group, Inc. on behalf of Bayer HealthCare LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of iron oxide yellow.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0159, is available at <http://www.regulations.gov> or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0159 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0159, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of April 25, 2016 (81 FR 24042) (FRL-9944-86), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10884) by Technology Sciences Group, Inc. (1150 18th Street, N.W., Suite 1000, Washington, DC 20036) on behalf of Bayer HealthCare LLC (Animal Health, P.O. Box 390, Shawnee Mission, KS 66201-0390). The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of iron oxide yellow (CAS Reg. No. 20344-49-4), when used as an inert ingredient (colorant) in pesticide formulations intended for varroa mite control around bee hives at a concentration not to exceed 0.15% by weight. That document referenced a summary of the petition prepared by Technology Sciences Group on behalf of Bayer HealthCare Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. Comments were not received on the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for iron oxide yellow including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with iron oxide yellow follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse

effects caused by iron oxide yellow as well as the no-observed-adverse-effect level (NOAEL) and the lowest-observed-adverse-effect level (LOAEL) from the toxicity studies are discussed in this unit.

The acute oral toxicity in rats, mice and dogs is low for iron oxide yellow. In an eight-generation reproduction study with rats, iron oxide was administered in the feed at an estimated oral dose of 25 milligram (mg) iron/day. No signs of toxicity were evident, reproductive performance was not affected.

Ten dogs were fed, from 1 to 9 years, diets containing iron oxide. Daily consumption was estimated to be 428 mg/dog. Two dogs experienced minor irregularities with stools, no other toxicological adverse effects were seen.

Four dogs were injected (i.v.) weekly for 10 weeks until each dog had received a total of 0.5 to 1.0 g/kg. There were signs of retinitis pigmentosa however there were no negative effects in hepatic function tests and biopsies of the liver, spleen, pancreas and other organs. Hemochromatosis was not induced.

Iron oxide yellow is poorly absorbed by mammalian systems after ingestion but data indicate it can be absorbed as iron after solubilization in the stomach and reduction to the ferrous form in the duodenum. Absorption of ingested iron in mammalian systems occurs primarily in the upper small intestine. Iron absorption is tightly regulated biologically such that individuals with low body iron stores absorb more iron while those with excess iron stores absorb less iron. Iron balance in the body is maintained by regulation of iron absorption in the upper small intestine because there are no specific mechanisms to eliminate excess iron.

Iron is an essential element necessary for maintenance of mammalian metabolic

systems. Iron intake varies depending on the source of iron, the foods consumed with the iron, the iron oxidation state and the iron needs of the body. For instance, iron from animal origin (heme-iron) is more readily absorbed than iron from vegetable origins (5-20% for meats; 1-10% from vegetable iron). The non-heme iron absorption depends on solubilization of plant-based or inorganic iron in the stomach prior to entry in the intestines. Non-heme iron from ferrous salts is more readily absorbed than iron from ionizable ferric salts, and iron from ferric oxides and hydroxides is the least readily absorbed. Non-heme iron is transported into the duodenal mucosal cells via a transmembrane metal transporter protein that is upregulated when body iron stores are low and down-regulated when body iron stores are high. This mechanism minimizes the likelihood of excess systemic exposure to iron.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of

the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

An acute effect was not found in the database therefore an acute dietary assessment is not necessary. A NOAEL has not been identified for risk assessment purposes. However, the acceptable daily intake (ADI) level identified by the World Health Organization Joint Expert Committee on Food and Agriculture is used as a safe exposure level for risk assessment purposes.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to iron oxide yellow, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from iron oxide yellow in food as follows:

Dietary exposure (food and drinking water) to iron oxide yellow could occur following ingestion of honey with residues from treated beehives. Because no adverse effects attributable to a single exposure of iron oxide yellow are seen in the toxicity databases, an acute dietary risk assessment is not necessary. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 3.16, and food consumption information from the U.S. Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). One hundred percent crop treated was assumed, default processing

factors, and tolerance-level residues for honey and use limitations of not more than 0.15% by weight in pesticide formulations.

2. *Dietary exposure from drinking water.* For the purpose of the screening-level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for iron oxide yellow, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening-level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Iron oxide yellow might be used in inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home, personal (care) products, and cosmetics. The Agency conducted an assessment to represent worst-case residential dietary exposure from honey only. The Agency agrees with the World Health Organization Joint Expert Committee on Food and Agriculture opinion that there was no need for additional human absorption studies. The WHO JEFCA committee concluded that it is unlikely that intake of iron oxides from all sources would exceed the Acceptable Daily Intake of 0–0.5 milligram/kilogram/day (mg/kg/day). Thus the JEFCA committee did not prepare a toxicological monograph on the iron oxides.

4. *Cumulative effects from substances with a common mechanism of toxicity.*
Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish,

modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found iron oxide yellow to share a common mechanism of toxicity with any other substances, and iron oxide yellow does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that iron oxide yellow does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

<http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

Section 408(b)(2)(c) of the FFDCA provides that EPA shall apply an additional margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of iron oxide yellow, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different

margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicity database for iron oxide yellow contains an eight generation reproduction/developmental toxicity screening study with the rat. No signs of toxicity were evident and reproductive performance was not negatively affected. There is no indication of neurotoxicity or immunotoxicity in the available studies with dogs and rat therefore, there is no need to require neurotoxicity or immunotoxicity studies. Qualitative fetal susceptibility was observed in the 2-generation toxicity study in rats. However, concern for fetal effects are low since they only occurred in the presence of maternal toxicity and protecting against maternal toxicity will subsequently prevent fetal toxicity. In addition, the ADI of 0.5 mg/kg/day, will be protective of fetal effects. In addition, the Agency used conservative exposure estimates, with 100 percent crop treated (PCT), tolerance-level residues, conservative drinking water modeling numbers, and a worst-case assessment of potential residential exposure for infants and children.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term

risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, iron oxide yellow is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to iron oxide yellow from food (honey) and water will utilize 0.0 % of the ADI for children 1-2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Iron oxide yellow may be used as an inert ingredient in pesticide products that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food (honey). Using the exposure assumptions described above, EPA has concluded that the combined short-term food, water, and residential exposure result in aggregate MOEs of 6,758 for both adult males and females respectively. As the level of concern is for MOEs that are lower than 100, this MOEs is not of concern.

EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 4,347 for children. As the level of concern is for MOEs that are lower than 100, this MOEs is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Iron oxide yellow may be used as inert ingredients in pesticide products that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food (honey) and water. Using the exposure assumptions described above, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 6,758 for adult males and females. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 4,347 for children. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the data in the toxicological database iron oxide yellow is considered not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to iron oxide yellow residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of iron oxide yellow in or on any

food commodities. EPA is establishing a limitation on the amount of iron oxide yellow that may be used in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for use on growing crops or raw agricultural commodities after harvest for sale or distribution that exceed 0.15% of iron oxide yellow.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for iron oxide yellow (CAS Reg. No. 20344-49-4) when used as an inert ingredient (colorant) in pesticide products intended for varroa mite control around bee hives at a concentration not to exceed 0.15% by weight in the end-use product formulation.

VII. Statutory and Executive Order Reviews

This action establishes exemptions to the requirement for a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This

action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 24, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, add alphabetically the inert ingredient “Iron oxide yellow (CAS Reg. No. 20344-49-4)” to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
***	**	**
Iron oxide yellow (CAS Reg. No. 20344-49-4)	Not to exceed 0.15% by weight of pesticide formulation	Colorant in pesticide formulations for varroa mite control around bee hives
***	**	**

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